

REMARKS

Submitted herewith is a Petition to extend the time for responding to the Official Action from May 6 to June 6, 2005.

As a result of this amendment, the claims now in the application are claims 1-15, 18-42 and 45-62.

In the outstanding Official Action, the Examiner:

- (1) objected to the Information Disclosure Statement filed by Applicants because certain non-patent references cited in that statement were not submitted to the Patent and Trademark Office as required;
- (2) objected to claims 24 and 39 because of certain informalities and required correction;
- (3) rejected claims 1, 2, 6, 23-36, 43, 44, and 48-60 as indefinite under 35 U.S.C. 112;
- (4) rejected claims 1, 3-5, 7-9, 16, 23, and 37-40 under 35 USC 102(b) as being anticipated by Lemmen;
- (5) rejected claims 1-3, 6, 7, 15, 16-19, 22-24, 37, 38 and 48 under 35 USC 102(b) as being by unpatentable by Spitz et al.;
- (6) allowed claims 41, 42 and 45-47; and
- (7) indicated that claims 10-12, 14, 15, 20, 21, 25-36, 43, 44 and 49-60 would be allowed if rewritten to overcome the indefinite rejection and/or to include all of the limitations of the claims from which they depend.

In response to Item 1 above, submitted herewith are copies of all of the missing non-patent documents noted in paragraph 2 of the Official Action, with the following exceptions: (A) Print-outs of the four web-site citations could not be located and recent efforts to download those references from the web sites have been unsuccessful. (B) The last reference, i.e., the cited product literature of Neurotron Medical of Lawrenceville, NJ, appears to have been misplaced and a search for it

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has been unsuccessful. Copies of these missing documents will be supplied by Applicants if and when they are found.

In response to Item 2 above, Applicants have now amended claims 24 and 39 to eliminate the Examiner's objection. These claims are now believed to be allowable.

In response to Item 3 above, Applicants have now amended certain of the listed claims to more clearly define the present invention with respect to the prior art of record.

In response to items 4 and 5 above, Applicants respectfully request reconsideration of the rejections on the basis of the foregoing changes made to the claims and the arguments presented hereinafter.

In response to Item 6, Applicants acknowledge allowance of claims 41, 42 and 45-47.

In response to Item 7, Applicants respectfully request reconsideration of the rejection of claims 10-12, 14-15, 20, 21, 25-36, and 49-60 under 35 U.S.C. 112 in view of the changes made to those claims or the claims from which they depend. It is believed that the various objections of indefinite language noted by the Examiner have been addressed and overcome by the change effected by this amendment.

Further in response to Item 4, namely, the rejection under 35 U.S.C. 102(b) based on Lemmen ('902), Applicants note that the reference discloses apparatus for use in nerve conduction studies including electrodes which are adjustably positionable with respect to one another using a fixture configured to indicate the distance between the electrodes. However, Applicants Lemmen does not disclose a sensor comprising a stimulator, a detector, and connector configured to automatically position the detector substantially adjacent to a second anatomical site when the stimulator is positioned substantially adjacent to a first anatomical site inasmuch as the fixture of Lemmen is configured to adjustably position the electrodes with respect to one another.

Claims 1, 3-5, 7-9, 23, and 37-40 have been amended directly, or by virtue of amendment of parent claims, to distinguish Applicants' invention from the apparatus disclosed by Lemmen ('902). Thus, for example, claim 1 calls for a connector for positioning the detector substantially adjacent to a second anatomical site when the stimulator is positioned adjacent a first anatomical site, with the connector including embedded conductors. That combination is neither taught nor rendered obvious by Lemmen. Further by way of example, claims 3 calls for the connector to be flexible. That limitation in combination with the other limitations of claim 3 also is neither taught nor rendered obvious by Lemmen. Other changes of like or different import have been made to the other apparatus claims rejected as fully met by Lemmen (see, for example, claims 37 and 40).

Accordingly, as presently amended claims 1, 3-5, 7-9, 23, and 37-40 are believed to distinguish patentably from Lemmen and to be in condition for allowance.

Further in response to Item 5 above, namely, the rejection under 102(b) based on Spitz et al ('100), Applicants acknowledge that the reference discloses a nerve condition monitoring system that comprises a housing 10 which serves as a support for stimulating electrodes 44 and pickup (detector) electrodes 40, with the stimulator and pickup or detector electrodes being coupled to electronic means for energizing the stimulating electrodes 44 and processing the signals sensed by the pickup electrodes 40. The housing 10 also has two surfaces 16 and 24 that are disposed at an angle to one another, with the stimulator electrodes 44 protruding from the surface 16 and the detector electrodes 40 positioned at a specified part of the surface 24.

However, apparatus disclosed by Spitz et al. is limited in its application, being designed for the sole purpose of monitoring nerve conduction velocity through the carpal tunnel of a patient, with the detector electrodes 40 being in a fixed position relative to the stimulator electrodes 44 and surfaces 16 and 24 serving as receiving supports for the forearm and hand respectively of the patient. The Spitz et al. apparatus is not designed to accomplish nerve conduction studies of other parts of

the human body in the same manner as is possible with Applicant's unique apparatus. The device of Spitz et al. is bulky and lacks the advantages offered by Applicant's device.

Applicant believes that as herein amended claims 1-3, 6, 7, 15, 18, 19, 22-24, 37, 38 and 48 clearly distinguish patentably from the apparatus disclosed by Spitz et al.

Claim 1 distinguishes from Spitz et al. calling for a stimulator shaped to fit a first anatomical site, a detector shaped to fit a second anatomical site, and a connector extending between the stimulator and the detector and configured to automatically position the detector substantially adjacent to the second site when the stimulator is positioned adjacent to the first site, with the connector including embedded electrical conductors connecting the stimulator and detector, and further including a processor connected to the detector for processing the response signals generated in response to the stimulus, with the processor being adapted to selectively process the response signals to provide a signal characteristic of the second anatomical site. That combination of features is not disclosed or rendered obvious by Spitz et al.

Claim 2 is believed to be allowable over Spitz et al. since it calls for a processor connected to the detector for processing the response signals of the detector and selecting from those signals at least one response signal characteristic of the second anatomical site. That feature is not believed to be disclosed by Spitz et al.

Claim 3 is similar to claim 1 except that it calls for flexible connecting means structurally connecting the stimulator to the detector, with the connecting means including electrical conductors coupled to the stimulator and the detector and being shaped so as to automatically position the detector substantially adjacent to the second anatomical site when the stimulator is positioned substantially adjacent to the first anatomical site.

Claim 6 depends from claim 3 and further distinguishes from Spitz et al. by calling for a processor coupled to the detector for processing, at least one signal generated in response to the stimulus that is characteristic of the second anatomical site.

Claim 7 depends from claim 3 and is believed to be allowable for the same reason as claim 1.

Claims 15, 18, 19 and 22 all depend from claim 3 and are believed to be allowable for the same reasons as claim 3 and also because they add other limitations that distinguish patentable from Spitz et al.

Method claim 23 calls for assessing physiological function in an individual using a sensor that comprises a stimulator, a detector, and a flexible connector formed integral with and serving as a mechanical and electrical connection between the stimulator and the detector, with the connector being configured to automatically position the detector substantially adjacent to a second anatomical site when the stimulator is placed substantially adjacent to a first anatomical site. That method is neither disclosed nor rendered obvious by Spitz et al.

Claim 24 depends from claim 23 and comprises additional steps relating to processing the response signals detected by the electrodes of the detector, determining from those response signals at least one electrode detecting a response signal characteristic of the second anatomical site, and then performing the nerve conduction studies using the electrode that detects a response signal characteristic of the second anatomical site. The steps called for by claim 24 clearly are neither disclosed nor rendered obvious by Spitz et al.

Claim 37 distinguishes from Spitz et al. in that it characterizes the claimed apparatus as comprising multiple layers of materials (see Applicants' Fig. 2A), including a flexible base layer that forms part of the stimulus means, the detecting means, and the connecting means. That feature is completely foreign to what is disclosed by Spitz et al.

Claim 38 depends from claim 37 and adds a further limitation of electrical processing means. Claim 38 is believed to be allowable for the same reasons as claim 37.

Claim 48 has been amended to better distinguish the claimed method from Spitz et al. As now amended, claim 48 requires a sensor that has flexible connector means connecting the stimulator and the detector to form an integral structure, with the connector means being shaped to automatically position the detector substantially adjacent the second anatomical site when the stimulator is placed substantially adjacent a first anatomical site. Applicant submits that claim 48 clearly defines a method that is neither disclosed nor rendered obvious by Spitz et al.

New claims 60 and 61 are patentable over the prior art of record because of the requirement that the sensor be formed from multiple layers of material.

In view of the foregoing, Applicants believe that this amendment places the application in condition for allowance. Therefore prompt and favorable reconsideration is solicited.

In the event that any fees may be required in this matter, please charge the same to Deposit Account No. 16-0221.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Nicholas A. Pandiscio', written in a cursive style.

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